

REMARKS

Claims 1-45 are pending in the present application. In this amendment in response to the Office Action mailed on January 3, 2002, Applicants have amended claims 1-3, 16-18, and 31-33. These amendments are made to correct typographical errors in the claims as originally filed. Support for the changes to these claims is found in the present specification at page 8, lines 18-25, and thus the proposed amendments do not introduce new matter. Entry of the amendments to claims 1-3, 16-18, and 31-33 is therefore respectfully requested.

Response to Restriction Requirement

The Office Action separates the claims into 14 separate groups. The first seven of these groups relate to polypeptides, and the last seven relate to the nucleic acids encoding each of the seven polypeptides. The Office Action holds that the separate nucleic acids and polypeptides are patentably distinct inventions because they "bear distinct structural or biochemical properties as evidenced by the separate sequences". Applicants traverse this requirement, because the restriction requirement is contrary to the Patent Office's own practice with respect to such sequences. Furthermore, the Office Action does not demonstrate there would be a serious burden on the Examiner. Notwithstanding the traversal below, should the restriction requirement be maintained, Applicants elect to pursue prosecution of the polypeptide sequence of Group VII, encompassing claims 1, 14, 15, 16, 29, and 30.

1. The Restriction Requirement is Contrary to the Patent Office's Own Practice with Respect to Examination of Multiple Sequences in an Application

As noted in MPEP 803, there are two elements of a proper restriction requirement. A proper restriction requirement requires a showing that there are two or more distinct or independent

inventions. A proper restriction requirement also and further requires a showing that there would be an undue burden on the Examiner in the absence of restriction. Without admitting that the inventions are not patentably distinct, Applicants nonetheless submit that the restriction requirement is improper, because the division of the claims into separate inventions based solely on the fact that they constitute different sequences is improper under the Patent Office's own guidelines. Applicants direct the attention of the Examiner to MPEP 803.04, which states "...the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application." The cited MPEP section states, in the next paragraph, that "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." The MPEP further states restriction to fewer than ten sequences should be required only in extraordinary cases, such as when the nature of the claimed material is complex (using the example of a protein amino acid sequence reciting three-dimensional folds). See also "Examination of Patent Applications Containing Nucleotide Sequences", 1192 O.G. 68 (November 19, 1996) (copy attached).

This MPEP section does not state that this provision applies only to cases wherein the claimed sequences do not comply with the utility provisions of 35 U.S.C. §§101 and 112. Applicants find no basis in MPEP 803.04 for limiting the application of this section to situations in which the claimed sequences suffer from a lack of utility. The utility requirements are separate and distinct from the requirement that a patent be awarded for a single invention; the same searches would have to be performed whether the utility requirements are satisfied or not. Satisfying a

requirement for patentability that is independent of and unrelated to the “single invention” rule should not matter to a determination of whether the claimed inventions are independent or distinct.

The Office Action applies identical reasoning to the assessment of the independence and distinctiveness of polypeptide sequences and nucleotide sequences. Consequently, there is no reason why the reasoning applied to the determination of a reasonable number of nucleotide sequences searchable in a single application in MPEP 803.04 is inapplicable to polypeptide sequences. Since the rationale for determination of a reasonable number of sequences applies equally well to polypeptide sequences as to polynucleotide sequences, examination of up to ten polypeptide sequences should also be deemed a reasonable number for examination purposes. Accordingly, Applicants respectfully submit that restriction of the present claims is improper as being contrary to Patent Office practice.

2. The Office Action Fails to Demonstrate An Undue Burden on the Examiner

Applicants respectfully submit that even if the claims of the present application encompass independent or distinct inventions as proposed in the Office Action, there is no undue burden that would be imposed on the Examiner if all the claims were examined, or alternatively, if all the claims directed to one or the other of the polypeptide sequences or the polynucleotide sequences were examined. A showing of an undue burden on the Examiner requires that the claimed inventions require different classification, or have attained separate status in the art, or would require different fields of search. MPEP 803. Applicants first note that each of the seven polypeptide sequences are classified in the same group (class 424, subclass 190.1), and each of the seven nucleic acid sequences likewise are classified in the same group (class 536, 23.7). Were the claimed sequences

to be deemed separate inventions based on the differences between polypeptide sequences and polynucleotide sequences, Applicants would agree that the separate inventions require different classification. However, each sequence has been deemed to be a separate invention. Since seven polypeptide sequences would require that only a single class and subclass would have to be searched, an undue burden based on separate classification of each polypeptide sequence has not been demonstrated. Similarly, since seven polynucleotide sequences would require that only a single class and subclass would have to be searched, an undue burden based on separate classification of each polynucleotide sequence has not been demonstrated. However, the Office Action fails to demonstrate that the inventions of Groups I through VII are separately classified. Similarly, the Office Action fails to demonstrate that the inventions of Groups VIII through XIV are separately classified.

Applicants further note that the claimed inventions have not attained a separate status in the art. There is no explanation provided in the Office Action of a separate inventive effort by inventors (MPEP 808.02). The separate status referred to in the Office Action (page 5) is based upon separate classification of polypeptide sequences and polynucleotide sequences, and does not demonstrate separate classification of separate sequences within these groups. Thus, there is no basis for concluding that the separate sequences within these groups have attained a separate status. In fact, there is not even a basis for concluding that the polypeptide sequences have attained a separate status in the art from the polynucleotide sequences, since it is easy to infer a polypeptide sequence from a given polynucleotide sequence.

Moreover, the Office Action does not demonstrate that searching these sequences will entail searching in different fields, because a search for one sequence (within a group) will not entail

searching in places where no prior art pertaining to the other sequences within the same group would be found. *Id.* Therefore, because there is not serious burden on the Examiner in searching the separate polypeptides or nucleic acid sequences, the restriction requirement is improper. Furthermore, the Office Action does not demonstrate that a search for either the polypeptide sequences or the polynucleotide sequences will entail searching in places where no prior art pertaining to the other would be found. Therefore, there is no showing that a search for any of the designated groups will entail searching in different fields. Accordingly, Applicants respectfully submit that restriction of the present claims is improper, because in the absence of restriction there would be no undue burden on the Examiner.

Should the Examiner agree that the claims are more properly grouped together as drawn to either the polypeptides or the nucleotides encoding the polypeptides as separate inventions, Applicants elect to pursue prosecution of the polypeptides, as exemplified by claims 1-30. As argued above, the seven polynucleotide sequences recited in the application should be considered to be a reasonable number for inclusion in a single application, since there would not be an undue burden on the Examiner.

A check in the amount of \$200.00 is enclosed to cover the fee for a two-month extension of time for response to the January 3, 2002 Office Action. No further fee is believed to be required in this response to this Office Action. However, should a fee for submission and entry of this response be required, the Commissioner is authorized and requested to charge any amounts due on account of the present submission, including any additional extension of time fees, to the Deposit Account of the undersigned attorneys, which is: **Deposit Account No. 12-2475.**

Should the Examiner have any further comments or questions, or believe that certain actions would expedite the issuance of the present application, the Examiner is invited to telephone the Applicant's representative at the number listed below.

Respectfully submitted,

LYON & LYON LLP

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By: Charles M. Doyle
Charles M. Doyle
Reg. No. 39,175

633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(914) 681-8851

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A [*Borellia burgdorferi*] *Borrelia burgdorferi* epitope polypeptide with an amino acid sequence selected from the group consisting of:
[VQEGVQQEQAQQP-(beta-A)(beta-,4)C] VQEGVQQEQAQQP-(beta-A)(beta-A)C; EIAAKAIGKKIHQNNG-(beta-A)(beta-A)C; ISTLIKQKLDGLKNE-(beta-A)(beta-A)C; PWAESPKKPE-(beta-A)(beta-A)C; DKKAINLDKAQQKLD-(beta-A)(beta-A)C; ITKGKSQKSLDG-(beta-A)(beta-A)C; and GMTFRAQEGAFLTG-(beta-A)(beta-A)C.
2. (Amended) The composition of matter of claim 1, wherein said epitope polypeptide comprises [VQEGVQQEQAQQP-(beta-A)(beta-,4)C] VQEGVQQEQAQQP-(beta-A)(beta-A)C.
3. (Amended) The composition of matter of claim 1, wherein said epitope polypeptide consists essentially of [VQEGVQQEQAQQP-(beta-A)(beta-,4)C] VQEGVQQEQAQQP-(beta-A)(beta-A)C.
16. (Amended) A vaccine for immunizing against or treating for Lyme disease, the vaccine comprising an epitope polypeptide with an amino acid sequence selected from the group consisting of: [VQEGVQQEQAQQP-(beta-A)(beta-,4)C] VQEGVQQEQAQQP-(beta-A)(beta-A)C; EIAAKAIGKKIHQNNG-(beta-A)(beta-A)C; ISTLIKQKLDGLKNE-(beta-A)(beta-A)C; PWAESPKKPE-(beta-A)(beta-A)C; DKKAINLDKAQQKLD-(beta-A)(beta-A)C; ITKGKSQKSLDG-(beta-A)(beta-A)C; and GMTFRAQEGAFLTG-(beta-A)(beta-A)C.

17. (Amended) The vaccine of claim 16, wherein said epitope polypeptide comprises [VQEGVQQEGAAQP-(beta-A)(beta-,4)C] VOEGVQQEGAAQP-(beta-A)(beta-A)C.
18. (Amended) The vaccine of claim 16, wherein said epitope polypeptide consists essentially of [VQEGVQQEGAAQP-(beta-A)(beta-,4)C] VOEGVQQEGAAQP-(beta-A)(beta-A)C.
31. (Amended) The nucleic acid sequence coding for a [*Borellia burgdorferi*] *Borrelia burgdorferi* epitope polypeptide with an amino acid sequence selected from the group consisting of: [VQEGVQQEGAAQP-(beta-A)(beta-,4)C] VOEGVQQEGAAQP-(beta-A)(beta-A)C; EIAAKAIGKKIHQNNG-(beta-A)(beta-A)C; ISTLIKQKLDGLKNE-(beta-A)(beta-A)C; PWAESPKKPE-(beta-A)(beta-A)C; DKKAINLDKAQQKLD-(beta-A)(beta-A)C; ITKGKSQKSLDG-(beta-A)(beta-A)C; and GMTFRAQEGAFLTG-(beta-A)(beta-A)C.
32. (Amended) The composition of matter of claim 31, wherein said epitope polypeptide comprises [VQEGVQQEGAAQP-(beta-A)(beta-,4)C] VOEGVQQEGAAQP-(beta-A)(beta-A)C.
33. (Amended) The composition of matter of claim 31, wherein said epitope polypeptide consists essentially of [VQEGVQQEGAAQP-(beta-A)(beta-,4)C] VOEGVQQEGAAQP-(beta-A)(beta-A)C.